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13. ABSTRATE (Progress Pepore Covers the third year of existence of the Center for Prostate Disease Research (CPDR), a collaborative research program of the Uniformed Services University of the Health Sciences (USUHS), the Walter Reed Army Medical Center (WRAMC) and Institute of Research (WRAIR), and the Armed Forces Institute of Pathology (AFIP). The Center is involved in the study of the molecular biology of prostate disease through laboratory activities at USUHS and the clinical study of prostate patients and pathology of the prostate at WRAMC and AFIP. The main goal of CPDR is to integrate both basic and clinical study of prostate cancer to bring basic science advances to the clinical benefit of prostate cancer patients.

During this report, period the CPDR has made a number of important scientific advancements related to clinical and basic science studies of prostate cancer. The clinical database of DoD prostate cancer patients has grown to over 2,500 cases and has been used for important studies. Most notably, we have discovered that African American prostate cancer patients have higher prostate specific antigen (PSA) levels due primarily to larger primary tumor size. This work was published this year in a feature article in The Journal of the American Medical Association. The database continues to expand and will provide outstanding ongoing clinical research opportunities. The basic science laboratory program has also excelled. The p53 tumor suppressor gene activation has been characterized in prostate cancer, been found to be an important prognostic marker in early stage disease treated by surgery, and formed the basis for exciting pre-clinical studies of p53-adenovirus gene therapy. Other gene alterations including bcl-2, p16, and androgen receptor have been studied in prostate cancer and many ongoing molecular investigations are in progress.

Overall, the CPDR is becoming recognized as a world-class prostate cancer research program and is providing positive recognition for WRAIR, USUHS, WRAMC, AFIP, and the USAMRMC

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PI - Signature

Date

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I. INTRODUCTION/SUMMARY STATEMENT

This progress report covers the third year of existence of the Center for Prostate

Disease Research (CPDR), a collaborative research program of the Uniformed Services

University of the Health Sciences (USUHS), the Walter Reed Army Medical Center

(WRAMC) and Institute of Research (WRAIR), and the Armed Forces Institute of Pathology

(AFIP). The Center is involved in the study of the molecular biology of prostate disease

through laboratory activities at USUHS and the clinical study of prostate patients and

pathology of the prostate at WRAMC and AFIP. The main goal of CPDR is to integrate both

basic and clinical study of prostate cancer to bring basic science advances to the clinical

benefit of prostate cancer patients.

The CPDR laboratory is housed in rooms A-3009 & A-3018 and contains approximately 1,500 sq. ft. of space within the Department of Surgery at USUHS and is a fully-equipped molecular biology laboratory. Five full-time researchers and several part-time

research students are utilizing this facility. The CPDR laboratory is also being utilized for training of Urology residents from Walter Reed in the field of molecular biology of prostate cancer. A formal memorandum of understanding for the National Naval Medical Center, Bethesda, MD, to participate in these efforts has been completed. CPDR clinical activities are based at the Urology Service, Department of Surgery at WRAMC. Three 150 sq. ft. offices houses five full-time employees and a number of part-time researchers. A comprehensive clinical database of all prostate cancer patients treated at WRAMC is underway which is integrated with pathologic and molecular studies.

II BODY

a) Personnel

NAME	FUNDING	START	STOP		JOB
	SOURCE	DATE	DATE	FT/PT	DESCRIPTION
Judd W. Moul, LTC, MC	Military	09/14/92	NA	FT	Director, CPDR
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Norman M. Rich, MD	USUHS	09/14/92	NA	PT	USUHS Senior Consultant
Sherry S. Osborne	USUHS	09/14/92	NA	PT	USUHS Administrator
Donald Sturtz, MD	USUHS	09/15/94	NA	PT	USUHS Consultant
F.K. Mostofi, MD	AFIP	09/14/92	NA	PT	Pathologist
Isabell A. Sesterhenn, MD	AFIP	09/14/92	NA	PT	Pathologist
Shiv K. Srivastava, PhD	HJF	05/01/93	NA	FT	Director, CPDR Laboratory
Jaya Gaddipati, PhD	HJF	10/01/93	NA	FT	Molecular Biologist
Dorothy Tong	HJF	05/01/94	8/1/95	FT	Molecular Biologist
Juli Harris, BA	HJF	10/01/93	9/4/95	FT	Clinical DBase Coordinator
Rene Mooneyhan, BA	HJF	06/20/94	NA	FT	Clinical DBase Researcher
Shirley L. Craig	HJF	05/09/94	NA	FT	Administrative Assistant
Denise Young	HJF	01/15/94	NA	PT	Pathology Technician
Roger Connelly, MS	HJF	09/19/94	NA	PT	Biostatistician
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Axel Heidenreich	German Gov't	08/01/95	NA	FT	Research Physician
Bridgit Heidenreich	Volunteer	11/01/95	NA	PT	Research Physician
Angela Pinto	HJF	10/14/95	NA	FT	Clinical Database Researcher
Howard Heidenberg, MAJ, MC	Military	07/01/93	NA	PT	Urology Research Resident
Michael Finger, MAJ, MC	Military	07/01/93	NA	PT	Urology Research Resident
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Marie Bettencourt, CPT, MC	Military	07/01/95	NA	PT	Urology Research Resident
Ted Morgan, CPT, MC	Military	07/01/95	NA	PT	Urology Research Resident
Robert Wheelock, PhD	HJF	09/01/95	NA	FT	Molecular Biologist

b) Programs/Projects

1. Prostate Cancer Clinical Database

A major CPDR initiative continues to be the collection of demographic, medical, pathologic, and outcomes data on all prostate cancer patients treated at WRAMC and to expand this collection to other DoD health care facilities. The project has a retrospective component (collecting data on all patients treated at WRAMC since 1980), and a prospective component focusing on complete data collection of all patients seen since 1 January 1994. This project has been approved by the

Department of Clinical Investigation (DCI) at WRAMC and copies of current data collection forms are attached as Addendum

1. The forms have been used both for patient care progress notes and for CPDR data collection. Hard copy research files have been established for over 2500 patients and are housed in the CPDR office at WRAMC. Data entry with quality assurance and security precautions are utilized to enter data into a relational database with database support assistance from WRAMC. WRAMC is the alpha-site for this clinical data collection and the system will be exported to other DoD facilities for similar data collection. During this reporting period Madigan Army Medical Center (Site coordinator: Brantley Thrasher, MAJ, MC, USA); Wilford Hall USAF Medical Center (Site coordinator: Paul Friedrichs, MAJ, MC, USAF) and National Naval Medical Center (Harold Frazier, CDR, MC, USN) had the CPDR Database protocol approved by their respective Institutional Review Boards and began collecting standardized data on PC patients. In addition, Brooke AMC, Malcolm Grow USAF Medical Center, Dewitt ACH, Kimbrough ACH and San Diego Naval Hospital have all agreed to join the project. Madigan AMC has been chosen as the Beta-site and will be the first center to link up to CPDR via the Internet. During this third year of operation, CPDR has seen the database initiative show benefit. Sufficient numbers of patients have been entered into the database such that research reports can be generated and are meaningful. For example, we have analyzed all PC patients treated at WRAMC between 1990-1994 with emphasis on PC in African American men. An important research study examining prostate-specific antigen (PSA) and tumor volume in black males was published in an October 1995 issue of the prominent Journal of the American Medical Association. As more patients from multiple sites are entered, this research database will be a valuable national resource.

2. Prospective Prostate Cancer Tissue Collection Project

In collaboration with the AFIP, all radical prostatectomies performed for prostate cancer at WRAMC are processed for CPDR research per a WRAMC DCI-approved protocol. AFIP pathology personnel come into the operating room and immediately collect fresh prostate cancer tissue and snap-freeze it for future molecular study. A strict protocol is followed for whole-mounting of the specimens for pathologic research studies. Multicentricity and volume of the tumor are determined, and tissue sections are processed for various immunohistochemical studies. As of the end of this report period, over 150 prospective specimens have been collected and cataloged. These tissues serve as the basis for CPDR laboratory studies at USUHS. Recently CPDR began collecting a portion of prostate tumor from each case for short-term cell culture and gene-therapy studies. These valuable tissues have already led to important discovery. We have been able to find racial disparity in prostate cancer volume in black and white men undergoing radical prostatectomy. Even in the equal-access US Military health-care system, African American men had larger tumors and more adverse pathologic features. Investigation is ongoing.

3. CPDR Molecular Biology Laboratory

The ongoing initiative at USUHS is involved in the study of oncogenes, tumor suppressor genes, and other molecular markers and factors in prostate cancer and benign prostate diseases. The following is a listing of ongoing projects:

a. Alterations of cell cycle check-point (ccc) genes in prostate cancer.

Cell cycle check-point control appears to provide control points within the cell cycle

and that appears to play a key role in maintaining the integrity of the cellular genome. Since mutational events represent one of the key molecular defects in the genesis of human cancer, our group has been studying the possible molecular defects of some ccc genes: p53, p16 and WAF/Cip1 in prostate cancer.

a-1. P53 tumor suppressor gene - a survey of tumor suppressor gene p53 mutations in various stages of prostate cancer utilizing immunohistochemistry and gene sequencing has been completed and has been published during the reporting period (Heidenberg, et al. - see below). Our studies have shown the involvement of p53 gene alterations in a high fraction of hormone refractory prostate cancer. More importantly, we have shown that the measurement of alterations of p53 in the primary tumor is a useful prognostic marker to predict recurrences after radical prostatectomy (Bauer, et al. - see below). This work with p53 has been expanded by also examining for bcl-2 oncogene expression to determine if the combination of biomarkers are of prognostic value. In a very important study of 175 men, p53 and bcl-2 were both of prognostic value to predict cancer recurrence after surgery (Bauer, et al. - see below).

a-2. p16 Gene

The p16 (MTS1) gene product is a negative regulator of the cell cycle and has been shown to be deleted or mutated in a number of tumor cell lines and primary tumors. There has been no comprehensive study of p16 gene alterations in prostate cancer. To determine the status of the p16 gene in human prostate cancer, metastatic prostate cancer cell lines and microdissected

primary tumor specimens and adjacent normal tissues from prostate cancer patients were analyzed. Although a point mutation in p16 coding sequence was detected in a metastatic prostate cancer cell line, we did not find mutations of the p16 protein coding sequence in primary prostate cancer specimens (see below Gaddipati et al.). The absence of mutation in p16 protein coding sequence in prostate cancer specimens and a low frequency of p16 mutation in metastatic cell lines suggest that such p16 alterations do not play a major role in the genesis of primary prostate cancer. However, using a new microsatellite marker, microdeletions of p16 gene locus are reported in about 50% prostate cancer and such studies are ongoing using in situ analysis for p16 gene in both primary and metastatic cancer specimens.

b. Elucidation of molecular mechanisms involved in hormone refractory prostate cancer.

Androgen Receptor (AR) mutations in prostate cancer - earlier work by CPDR had suggested a mutational hot spot in the AR gene may be common in advanced prostate cancer. Later work, however, failed to show AR mutations in a larger cohort of over one hundred samples. These later findings will be the basis of a research publication during the fourth reporting period. Since AR mediated signal transduction plays a critical role in prostate cell proliferation and differentiation, we initiated a project evaluating alternative mechanisms of activation of the AR signalling pathway. The ongoing experiments will characterize the role of interactions of tyrosine kinase growth factor receptor and the androgen receptor.

c. Development of gene therapy strategies based on the molecular genetic alterations in prostate cancer.

p53 gene therapy of prostate cancer:

In collaboration with Dr. Prem Seth (Medicine Branch NIH), we have developed adenovirus vectors containing the tumor suppressor gene p53. We have obtained very exciting results in demonstrating that adenovirus p53 vectors have dramatic inhibitory effects on the growth of metastatic prostate cancer cell lines via induction of cellular p53 pathways (Srivastava, et al see below.) Further studies in the nude mouse animal model of prostate cancer have shown significant growth inhibitory effects (60-80%) in the progression of established tumors. Further studies of antitumorigenic effects of the adenovirus p53 vector in immune competent animals are currently in progress.

Additional studies are also in progress to follow up these observations in animal models and to design strategies for clinical trials. For this research, the CPDR has received a Research Award from the Association for the Cure of Cancer of the Prostate (CaP Cure) which was used to support ongoing studies during this reporting period.

d. Development of primary cell culture from prostate tumor specimens: We have established protocols for growing normal and prostate tumor derived cultures of epithelial cells. This work is extremely important for studies which require a pure population of tumor cells. This study also has utility for future testing of antitumor agents as there are very few prostate cancer cell lines available. We have also recently shown the cell growth inhibitory effects of the adenovirus p53 vector on primary

- prostate cell cultures of four patients who underwent radical prostatectomy.
- 3. Development of DNA/RNA bank from prostate cancer specimens.
 - As an ongoing function of the CPDR molecular biology laboratory, we have now prepared DNA specimens of carefully microdissected tumor and normal tissue sections from over fifty patients who had undergone radical prostatectomy at Walter Reed Army Medical Center. These specimens represent a long term resource for molecular characterization of prostate cancer. Additionally, we have prepared DNA and RNA from blood from over 90 patients which will be used as a source of constitutional or germ line DNA for determining genetic risk factors specifically in the African American population.
- 4. Research projects involving collaborations with outside researchers/institutions.
- a. RT-PCR of PSA gene to assess occult micrometastasis in prostate cancer. A VA research grant with the University of Washington, Seattle, and the Seattle VA Hospital was approved for \$65,000 for two years and work started during this reporting period. A total of 85 peripheral blood samples and 40 bone marrow samples have been collected for this project during the reporting period. Analysis and clinical correlation of results are in progress.
- b. Neural Network artificial intelligence computer programs to assess prostate cancer using clinical variables from the CPDR database. Collaboration with Kaman Sciences Corporation is ongoing to predict outcomes of CaP patients based on pre-treatment clinical and pathologic variables. The current model uses 38 input clinical and pathologic variables to predict cancer recurrence after radical prostatectomy. In a

- study group of approximately 220 patients, the model was able to correctly predict recurrence with approximately 90% accuracy. This model is currently being validated in a prospective manner.
- c. Cathepsin-D and EGFR expression in prostate cancer as prognostic markers.
 Collaboration with Medical College of Virginia and University of North Carolina.
 (One publication [see Maygarden, et al.], and a final report-second publication in press in the Journal of Urology [see Moul, et al.]).
- d. IGFII Receptor alterations in prostate cancer.Collaboration with Duke University Medical Center (ongoing).
- TGFB Receptor mutation and microsatellite instability in prostate cancer.
 Collaboration with National Cancer Institute, NIH Bethesda (ongoing).
- f. Prostate specific membrane antigen (PSMA) marker studies collaboration with Dr.

 Gerald Murphy, Pacific Northwest Cancer Institute, Seattle, WA. Ongoing research to determine the value of this serum marker in prostate cancer patients (see Douglas, et al.).
- g. Free PSA studies collaboration with Dr. Gerald Murphy (see above). Studies of prostate cancer patients to determine the value of measuring the free, unbound PSA in the serum versus the bound and total PSA concentrations.
- h. Clinical trials with Eastern Cooperative Oncology Group (ECOG) at WRAMC.

CONCLUSIONS

The Center for Prostate Disease Research (CPDR) program project has made significant progress in the third year of operations. Our mission to advance knowledge of prostate cancer and disease and to integrate clinical and basic science projects is continuing and expanding. The main advances during this reporting period have been the growth, maturity, and output of the CPDR clinical database, the studies of the p53 gene and other genetic alterations in prostate cancer, development of gene therapy experiments, and the general growth solidification of our program as a national resource for the study for prostate disease.

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- 5. Zhau, HE, Zhao, L, Chung, LWK, Shao, G, Troncoso, P, Kogima, M, Zehng, N, Moul, JW, et al: Comparative studies of prostate cancers among US, Chinese and Japanese patients: Characterization of histopathology, tumor angiogenesis and neuroendocrine factors. J Urol, 153:504A, 1995 (abstract No 1103).
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REGISTRATION

DIVISION:	WALTER REED AMC
Auton	nated Version of SF 600
	BBIA

Patient Rank: Officer Enlisted Mari Ethnic Origin: African-American Caucas		idowed Unk	Height:	ftin.
PATIENT MEDICAL HISTORY:				
Family History of CAP? No Yes Unk # of 1st degree affected: (Father, Brother, Son) # of 2nd degree affected: (Grandfather, Uncle, Cousin) Alcohol Use: Current Past Never Unk Cigs: Current Past Never Unk Pipe: Current Past Never Unk Cigars: Current Past Never Unk	Pre-tx Potency: No Yes Unk Treated BPH: No Yes Unk Treatment of BPH (Check all that apply): Alpha Block Surgery Other: Vasectomy: No Yes Unk Treatment of BPH (Check all that apply): Unk Age: 30 30-34 35-40 > 40	CAD: IN HTN: IN CVA: IN Renal Insuf.: IN Diabetes: IN Other Cancer: IN Specify:	No Yes	Unk Unk Unk Unk Unk Unk Unk Unk
GU SYMPTOMS: Yes No Prostatism: No Yes Unk Prostatitis: No Yes Unk SX of Metastases: No Yes Unk Hematospermia: No Yes Unk Gross Hematuria: No Yes Unk REASON FOR BIOPSY: ABN DRE: No Yes Unk Elev. PSA: No Yes Unk Other: No Yes Unk Specify: PRE-BIOPSY PSA: M SOAP NOTE:	Number of Biopsies: Previous Biopsy: No Yes Previous Trus: No Yes Biopsy Performed at: WRAMC Location of Pos Biopsy (Worst grade, worst gleasor LEFT SIDE: Neg Pos Not Done Grade: W M P Gleason Sum: RIGHT SIDE: Neg Pos Not Done Grade: W M P Gleason Sum: UNKNOWN SIDE: Neg Pos Not Appl. Grade: W M P Gleason Sum:	Specific L. Apex R. Apex BIOPSY 1 TRUS-Fi 2 Vol:	Location (if knd L. Mid L. R. Mid R. TYPE (Cirindings: Neg	own): Base L. SV Base R. SV cle): Pos Unk
Patient Name:	SSN:	Date of Birth:	DM	Y
Current Address:				
Home Phone:	Work Phone :Physician's Signature:	·		Revised 12/9

WALTER REED ARMY MEDICAL CENTER

DIVISION: WALTER REED AMC

MRI-Pelvis: Neg Pos ND Pending MRI-Transrectal: Neg Pos ND Pending CT Scan ABD: Neg Pos ND Pending CT Scan Pelvis: Neg Pos ND Pending CXR: Neg Pos ND Pending D2 T1b T3b N0 M0 MC MC T1c T3c N1 M T2a T4a N2 T2b T4b N3 CXR: Neg Pos ND Pending D2 PRIMARY TREATMENT:		AMC	0.1000			STAGING	G				BBIA
Testosterone:DMY	PRETREATME	ENT LA	AB VAL	UES (C	heck all that ap	oply or enter	value if known):				
Pre-Tx PAP:DMY	Creatinine	ð:	D		M	_Y	Alk Phosphatase:		DI	м	_Y
RADIOLOGY: FINAL CLINICAL STAGE (PRE-TREATMENT):	Testostero	one:	D.		M	_Y	Pre-Tx PSA:		D_ ·1	М	Y
RADIOLOGY: Bone Scan: Neg Pos ND Pending MRI-Pelvis: Neg Pos ND Pending MRI-Transrectal: Neg Pos ND Pending CT Scan ABD: Neg Pos ND Pending CT Scan Pelvis: Neg Pos ND Pending	Pre-Tx P	AP:	D		M	_Y					
MRI-Pelvis: Neg Pos ND Pending A2 C2 T1b T3b N0 M0 MRI-Transrectal: Neg Pos ND Pending B0 C3 T1c T3c N1 M CT Scan ABD: Neg Pos ND Pending B1 D0 T2a T4a N2 CT Scan Pelvis: Neg Pos ND Pending B2 D1 T2b T4b N3 CXR: Neg Pos ND Pending D2 T2c PRIMARY TREATMENT:	RADIOLOGY:					A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	the contract of the contract o	Carterian Land State Control #	A P. C. Comp. Co. Co. Co. Co. Co. Co. Co. Co. Co. Co	and the first of the contract of the	
MRI-Transrectal: Neg Pos ND Pending B0 C3 T1c T3c N1 M CT Scan ABD: Neg Pos ND Pending B1 D0 T2a T4a N2 CT Scan Pelvis: Neg Pos ND Pending B2 D1 T2b T4b N3 CXR: Neg Pos ND Pending D2 T2c PRIMARY TREATMENT:	Bone Scan:	Neg	Pos	ND	Pending	A1	C1	Tla	ТЗа	NX	MX
CT Scan ABD: Neg Pos ND Pending CT Scan Pelvis: Neg Pos ND Pending CXR: Neg Pos ND Pending	MRI-Pelvis:	Neg	Pos	ND	Pending	A2	C2	Т1ь	ТЗЬ	N0	М0
CT Scan Pelvis: Neg Pos ND Pending CXR: Neg Pos ND Pending D2 T2b T4b N3 T2b T4b N3 T2c PRIMARY TREATMENT:	MRI-Transrectal:	Neg	Pos	ND	Pending	B0	C3	Tlc	T3c	N1	MI
CXR: Neg Pos ND Pending D2 T2c IVP: Neg Pos ND Pending PRIMARY TREATMENT:	CT Scan ABD:	Neg	Pos	ND	Pending	B1	D0	T2a	T4a	N2	
VP: Neg Pos ND Pending PRIMARY TREATMENT:	CT Scan Pelvis:	Neg	Pos	ND	Pending	B2	D1	T2b	T4b	N3	
是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就 第一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就是一个人,我们就	CXR:	Neg	Pos	ND	Pending		D2	T2c			
	VP:	Neg	Pos	ND	Pending	PRIMA	RY TREATMENT				
CYSTO: Neg Pos ND Pending Prostatectomy Hormonal Radiation Watch Wait Cryo Decision	CYSTO:	Neg	Pos	ND	Pending	Prostatec	tomy Hormonal	Radiation	Watch Wait	Cryo	Decision P
SOAP NOTE:	SOAP NOTE:					J [T				-

Patient's Name:	Last Four:	Physician's Signature:

Patient's Name:	Last Four:	Physician:	
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RADICAL PROSTATECTOMY PELVIC LYMPHADENECTOMY

Date of Surgery:	DayN	MonthYear_					
Lymphadenectomy Only:	No Yes						
Operation Time: (Prostatectomy)	Hours	Minutes	•				
Lymphadenectomy:	Open	Laparoscopic	Not Done				
Type:	Retropubic	Perineal	Not Done-Abo	rted			
Nerve Sparing:	Unilateral	Bilateral	Not Done	Unk			
HCT: Pre-Op		Day	MonthYea	ar			
Post-Op (first value on post op day 1)							
Autologous Blood Collected: No Yes Unk # of Units							
Estimated Blood Loss (during	g surgery):	cc's					
Transfusion Units (intraoperation	ve): AUTO	Non AU	JTO	·			
Was Preoperative Hormone	e Manipulation U	sed? No Yes	Unk				
Type (Circle):	Flutamide	Proscar					
	Lupron	Zoladex					
	Other:		•				
Duration (weeks):_							
Comments:			И	VRAMC			

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Px to RTC in _____weeks.

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PROSTATE RADIATION TREATMENT SUMMARY Last Name: First Name: MI: SSN: ... Date of Birth: D____M___Y____ Diagnosis: Prostate Cancer Histology: Adenocarcinoma. Gleason Sum:__ Stage: T____N___M___. Tx prior to radiation therapy: From Biopsy Prostatectomy Pre-treatment Lab Values: PSA______. PAP_____. From Surgery Hormonal Therapy Start Date: D_______Y____. Elapsed Days_____. # of Fractions:_____. TREATMENT: (include start and stop date) Completion Date: D____M__Y Fraction Size: cGy Field Arrangement: Prescribed Dose: Field: Size: 4 Field Pelvis:____cGy Arc Prostate + SV:____cGy Other Specify: Energy: ≤10 MV Prostate:____cGy >10 MV Mixed TREATMENT RESPONSE: Rectal SX: Management: Other Diarrhea **Proctitis** G-U SX: Management: Frequency Dysuria Other Hematuria Management: Skin SX: No Yes Breaks in Treatment: Describe: No Yes

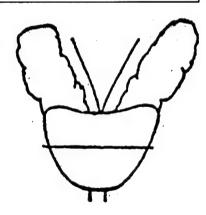
Physician Signature:

 WALTER REED ARMY MEDICAL CENTER Personal Data - Privacy Act of 1974 (PL 93-579) Urology Clinic-WRAMC DIVISION: WALTER REED AMC Automated Version of SF 600 BBIA

HORMONAL THERAPY

ORCHIECTOMY:	No	Yes	Date: D		M	Y	11/240				
Total:	No	Yes	Unk								
Subcapsular:	No	Yes	Unk								
Testicular Prostheses:	No	Yes	Unk		<u> </u>						
LH-RH: No Yo	es Da	ite Starte	d: D		Υ_		Date Termina	ed: D	M	Υ	
Type (Circle): Lupro	on Zo	oladex	Other:				•				
ANTIANDROGEN: N	o Yes	Date S	tarted: D_		M	_Y	. Date Ter	minated: D_	M	Y	
Type (Circle): Flutar	nide	Other:					•				
Clinical Trial Tx: No	Yes	Date	Started: D		M	Y	Date Ter	minated: D	M	Y	
Specify:	27 877 m										
Hormonal Failure Ther	apy:	No	Yes	Date St	tarted:	D	M	<u>Y</u>	11		
Antiandrogen V	Vithdrawal	: No	Yes	Unk							
Suramin:		No	Yes	Unk							
Chemotherapy:		No	Yes	Unk	If Yes,	Specify:_					<u></u>
Other:		No	Yes	Unk	If Yes,	Specify:_					•

SOAP NOTE:



Patient's Name:	Last Four:	Physician's Signature:

DIVISION: WALTER REED AMC Automated Version of SF 600

CPDR CYROTHERAPY TREATMENT SUMMARY

I. Primary Therapy: (If primary, comp	lete registration	and staging forms	and skip sectio	n II)
Date of Procedure: MDY Pr				
		D		
If yes:				
Pre-Cryo Hormonal Therapy: Yes No				
If yes, type:	☐ Flutamide	☐ Casodex	Other:	
If yes, duration:mos.				
IL Failure T	herapy: Yo	es No		
Specify FAILED XRT: Yes No (If failed XR	RT, complete XR'	Γ forms for 1° XRT)		
FAILED Other: Yes No Specify:				•
Recurrence Biopsy: Yes No Date: M				
Number of Cores:Number of l	Pos Cores:	*		
Biopsy Performed at: WRAMC Other:_		•		
Location of Pos Biopsy (Worst Grade, Worst Glea	son Sum):	Specific Location	(if known):	
LEFT SIDE: Neg Pos Not Done		L.Apex L.Mid	L.Base L.S	V
Grade: W M P Gleason Sum:		R.Apex R.Mid	R.Base R.S	SV
RIGHT SIDE: Neg Pos Not Done		BIOPSY TYPE (Circle):	
Grade: W M P Gleason Sum:		1 TRUS-Finding	,	Unk
		2 Digitally-Direc	_	
UNKNOWN SIDE: Neg Pos Not Appl.		3 TURP		
Grade: W M P Gleason Sum:		4 Other/Specify:		
ш. (Cryo Procedure			
Length (induction of anesthesia to leaving OR)	HR_	MIN		
Prostate Volume:cc Number of Insertion	Sites (Circle):	2 3	4 5	6 7
Operative Complication: Yes No If Yes, Specify	<i>r</i> :	Double Freeze Ap	ex: Yes	□ No
		Double Freeze Bas	se: 🗆 Yes	□ No
Surgical Notes: Yes No If Yes, Specify:		Pull Back:	☐ Yes	□ No
	•			
	Patient Name:			
	Current Address			
	Home Phone:		Work Phone	71.07
		[D_		
		ature:		

DIVISION: WALTER REED AMC Automated Version of SF 600

PROSTATE ULTRASOUND TRUS REPORT

Date of TRUS:	DM_	Y	Examiner/Physician:	
REASON FOR	TRUS:	Photo Torrest	Maria de la compania de la compania La compania de la co	
□ No □ Yes	Protocol:			
□No □Yes	Elevated PSA; s	pecify Pre-Biopsy PSA	DM	·
□No □Yes	PSA Velocity			!
□No □Yes	Abnormal DRE (check all that apply):	ocation: L. Apex L. Mid L. Base	L. SV Asymmetry
			☐ R. Apex ☐ R. Mid ☐ R. Base ☐]R. SV
		Presumptive DRE	Stage: B0/T1c B1 B2 C	
□No □Yes	Other, specify:			
TRUS BIOPSY	:	All Market		And the second s
□No □Yes	Biopsy Performed:	Location: L. Apex	L. Mid L. Base L. SV L. TZ	
		□ R. Apex	R. Mid R. Base R. SV R. TZ	☐ Other
Total Number of	f Cores:			
TRUS FINDING	GS:			
□No □ Yes	Abnormal Lesion	Location (check all th	at apply): L. Apex L. Mid L. Base	L. SV
			R. Apex R. Mid R. Base]R. SV
Volume:	cc's P	SA-D:	☐ Calculi ☐ Hypoechoic Nod. ☐ Hyper	echoic Nod. 🔲 Isoechoic Nod.
□No □ Yes	Previous Biopsy	#	Capsule:] Suspicious
□No □ Yes	Previous TRUS	#		
SOAP NOTE:	Antibiotic Prophylax	in annifu		
Patient Identifica		is, specify.	Follow-up (check one):	Final Path:
i acioni idonullo	VII.		Patient to call MD	CA: No Yes
			MD to call Patient	PIN: No Yes
			Patient to make F/U Appt.	1111. — 110 165
			Physician's Signature:	•

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PROSTATE CANCER FOLLOW-UP

DIVISION: WALTER REED AMC Automated Version of SF 600

Follow-up Date: DMY						············				
New Address: N Y Specify:						 •				
New Phone: N Y Specify:						 •				
REASON FOR FOLLOW-UP (CIRCLE AL		•								
Rad. Pros. XRT HT CRYO Watchfu	l Waiting Routi	ne Problem, If so	specify:							
RECURRENCE:										
First Serologic (PSA) Elevation Recurrence:	□ No □ Yes	First (Clinical Rec	urrence: No	Yes					
Date of Recurrence: MDY		Date of	of Recurrence	e: MD_	Y	 ·				
First Clinical/Serologic Recurrence RX (Circ	cle)	LABS:								
Hormonal Radiation Chemo		PSA:		D	Y	-				
Watchful Wait Cryo Other:	·	PAP:		MD	Y					
Type of First Clinical Recurrence:		HCT:		MD	Y					
Pos Bone Scan: No Yes		CR:		D	Y	·				
Local Recur.: No Yes		ALK PHOS:		D	Y					
Visceral Mets:	L	TESTOS:		D	Y	•				
Second Recurrence: No Yes Date:	: MD_	Y S _I	pecify:							
CONTINENCE/POTENCY:										
Continence: No Yes	Poteno	cy: No N	Yes							
If no, number of pads/day:		circle Tx: VET		nile Pros Nor	ne Other:					
If yes, month/year continent: MY										
A SAPAGON POPERA INTO A STRUCTURE A STRUCTURE A CONTRACTOR DE LA CONTRACTOR DE LA CONTRACTOR DE LA CONTRACTOR	registro do combina	. No. of the state				P788 18 Silvinini - 1 1 1 7				
COMPLICATIONS OF PRIMARY TREAT	MENT: 🔲 N	No 🔲 Yes			MERE Wee					
COMPLICATIONS OF PRIMARY TREAT	MENT: If Hormonal:	No Yes		If Radiation:						
	era John II., Gall III.	No	☐ Unk		□ No □ Yes	□ Unk				
If Prostatectomy:	If Hormonal:	□ No □ Yes	Unk	GI Symptoms:	□ No □ Yes					
If Prostatectomy: DVT/PE: No Yes Unk	If Hormonal: Hot Flashes:	□ No □ Yes	_	GI Symptoms: Specify:		·				
If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk	If Hormonal: Hot Flashes: Diarrhea:	No Yes No Yes No Yes	□ Unk	GI Symptoms: Specify: GU Symptoms:		Unk				
If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen	No Yes No Yes No Yes	☐ Unk ☐ Unk ☐ Unk	GI Symptoms: Specify: GU Symptoms:	□ No □ Yes	Unk				
If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk Specify:	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen Stopped:	No Yes No Yes No Yes No Yes No Yes No Yes	☐ Unk ☐ Unk ☐ Unk	GI Symptoms: Specify: GU Symptoms: Specify: PSA Nadir:	□ No □ Yes	Unk				
If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen	No Yes No Yes No Yes No Yes No Yes	☐ Unk ☐ Unk ☐ Unk	GI Symptoms: Specify: GU Symptoms: Specify:	□ No □ Yes	Unk				
If Prostatectomy: No Yes Unk DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk Specify: Other: No Yes	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen Stopped:	No Yes No Yes No Yes No Yes No Yes Yes Yes	☐ Unk ☐ Unk ☐ Unk	GI Symptoms: Specify: GU Symptoms: Specify: PSA Nadir:	□ No □ Yes	Unk				
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If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk Specify: Other: No Yes If Cryotherapy: No Yes Unk Yes	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen Stopped: Other: \(\sum \) No	No Yes No Yes No Yes No Yes No Yes Yes Yes	☐ Unk ☐ Unk ☐ Unk	GI Symptoms: Specify: GU Symptoms: Specify: PSA Nadir:	□ No □ Yes	Unk				
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If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk Specify: Other: No Yes If Cryotherapy: No Yes Unk Yes Yes Unk Yes Unk Yes Yes Yes Yes Yes Yes Yes Ye	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen Stopped: Other: \(\sum \) No	No Yes No Yes No Yes No Yes Yes Yes	☐ Unk ☐ Unk ☐ Unk	GI Symptoms: Specify: GU Symptoms: Specify: PSA Nadir: DM	□ No □ Yes Y	Unk				
If Prostatectomy: DVT/PE: No Yes Unk MI/Cardiac: No Yes Unk Rectal Injury: No Yes Unk BN Contracture: No Yes Unk Reoperation: No Yes Unk Specify: Unk If Cryotherapy: No Yes Unk SOAP NOTE:	If Hormonal: Hot Flashes: Diarrhea: Surgical: Gynecomastia: Antiandrogen Stopped: Other: \(\sum \) No	No Yes No Yes No Yes No Yes Yes Yes	Unk Unk Unk Unk	GI Symptoms: Specify: GU Symptoms: Specify: PSA Nadir: DM	□ No □ Yes Y	Unk				

WALTER REED ARMY MEDICAL CENTER Personal Data - Privacy Act of 1974 (PL 93-579) PROSTATE RADIATION THI	DIVISION: WALTER REED AMC Automated Version of SF 600 IERAPY FOLLOW-UP							
Name: SSN:	Prostatectomy: No Yes Date: D M Y							
Radiation Dose:cGy Completion Date: DMY	Past Hormonal Therapy: ☐ No ☐ Yes Currently: ☐ No ☐ Yes							
Original Stage: TNM	Orchiectomy: No Yes Date: D M Y							
PSA: Pre-treatment: Current:	Hormone Failure: No Yes							
INTERVAL HISTORY (Constitutional Complaints):								
Weight Loss: ☐ No ☐ Yes Fatigue: ☐ No ☐ Yes Night Sweats: ☐] No ☐ Yes Febrile Episodes:☐No ☐ Yes							
Bone Pain: No Yes Site of Bone Pain:								
GASTROINTESTINAL SYMPTOMS:	PHYSICAL EXAM:							
Constipation: No Yes Daily Weekly Monthly Less	Vital Signs: Temp: Pulse: Wt:							
BRBPR: No Yes Daily Weekly Monthly Less	Resp:B/P:							
Stool Incontinence: No Yes Daily Weekly Monthly Less	Lymphadenopathy:							
Melena:								
Rectal Pain: No Yes Daily Weekly Monthly Less	Abdomen:							
Diarrhea: No Yes Daily Weekly Monthly Less								
# stools/day	Musculo-skeletal:							
GENITOURINARY SYMPTOMS:								
Hematuria: No Yes Daily Weekly Monthly Less	Rectal: Tone:Guaiac:							
Urinary Frequency: No Yes Daily Weekly Monthly Less	Prostate:							
Dysuria: No Yes Daily Weekly Monthly Less								
Nocturia: No Yes Frequency (Episodes/night)								
Decreased Erectile Function: No Yes								
Erections: Normal Partial None								
Incontinence: No Yes Pads/day: One > One	e a							
FOLLOW-UP & DISPOSITION:								
Disease Status:								
NED: No Yes								
PSA: Rising Falling Stable								
Clinical Response: DRE: Normal Stable Better Worse								
D.M.: No Yes	Physician's Signature:							

 WALTER REED ARMY MEDICAL CENTER Personal Data - Privacy Act of 1974 (PL 93-579) Urology Clinic-WRAMC DIVISION: WALTER REED AMC Automated Version of SF 600 BBIA

CPDR NECROPSY FOLLOW-UP FORM

	DEATH INFO	RMATION A		2000 E.S.								
DATE OF DEATH: DMY			···ain									
PLACE OF DEATH:	CITY	STATE	•									
DEATH CERTIFICATE ATTACHED: Yes				1								
IF NO, PLEASE PROVIDE CONTACT FOR CPDR TO WRITE FOR CERTIFICATE:												
If 110, I DEADE I ROT IDE CONTACT FOR CLUB TO WRITE FOR CERTIFICATE.												
						•						
the second of th	USE OF DEATH	I (Please Check):										
☐1 FROM PROSTATE CANCER												
☐2 FROM OTHER CAUSE, Specify						•						
If other cause, was Prostate Cancer present at death:												
If Yes, Stage of Prostate Cancer at death:												
	FINAL CL	INICAL STAGE		FINAL TN	MSTAGE							
	A1	Cl	Tla	T3a	NX	MX						
	A2	C2	T1b	T3b	N0	M0						
	В0	C3	Tlc	T3c	N1	Mi						
	B1	D0	T2a	T4a	N2							
	B2	Di	T2b	T4b	N3							
		D2	T2c									
☐3 CAUSE OF DEATH UNKNOWN												
SOAP NOTE:												
•												
Patient's Name:	Last Four:	Physician's	Signature:									

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RADICAL PROSTATECTOMY PATHOLOGY

Primary Hospital Path. Accession Number:														
AFIP Referral: Yes No	AFIP Acc	cession	Number:											
OVERALL: (Circle Correct Answers)														
Capsule	Negativ	e	MicroInv.		Infilt.		Equivocal		Unilat		Bilat		Unk	
Margins	Negativ	e	Positive		Unilat		Bilat		Unk					
Seminal Vesicles	Negativ	e	Positive		Unilat		Bilat		Unk					
Nodes	Negativ	e	Positiv	e	Unilat		Bilat		Unk # of		f pos. n	odes:		
Worst Grade	Well		Moderate		Poor		Unk							
Worst Gleason	2 3	3	4	5	6	7	8	9	1	0	Unk			
Worst Nuc. Grade	1 2	2	3	Unk										
Urethra	Negative	e	Positive		Unk									
Bladder Neck	Negative	e	Positive		Unk									
Multifocal	No		Yes		Unk									•
Benign Tiss. in Margin	No		Yes		Unk									
# of Prostatic Tumors	1 2	2	3	4	5	6	7	8	9	10	>	10	Unk	
TUMOR SIZE(cc) L W H	ORGA CONFI			RST ADE	7		ST NU ADE	C		SIDE		LOC	ATIO	Ń
1xx	Yes	No	W	M	P	1	2	3	L	R	В	Α	M	В
2xx	Yes	No	w	M	P	1	2	3	L	R	В	Α	M	В
3xx	Yes	No	W	M	P	1	2	3	L	R	В	Α	M	В
4xx	Yes	No	W	M	P	1	2	3	L	R	В	Α	M	В .
5xx_	Yes	No	W	M	P	1	2	3	L	R	В	A	M	В
Total Prostate Weight		grams												
Final Pathological Stage:	(A1)	(A2)	В1	В	2	С	C1	С	2	C3	D1	D2	DO	i
Final TNM Pathological Stage:	(T1a)	(T1b)	(Tlc) T	2a	T2b	T2c	T	3a	T3b	ТЗс	T4a	T4	b
	NX	N0	NI	N	2	N3								
	MX	M0	M1											
Patient's Name:							SS	N:						·